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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,717	06/05/2006	Jinichiro Koga	Q95277	3601

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,717	KOGA ET AL.	
	Examiner	Art Unit	
	CHRISTIAN L. FRONDA	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *7-15 and 19-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-28 as listed in the claim set filed 07/30/2008 are pending. Claims 7-15 and 19-28 have been previously withdrawn from consideration as drawn to a non-elected invention.

2. Claims 1-6 and 16-18 are under consideration in this Office Action. The previous grounds of rejection under 35 U.S.C. 112, first paragraph, have been withdrawn in favor of the new grounds of rejection as presented in the instant Office Actions.

3. The objection to claim 16 for depending from nonelected claim 15 has been withdrawn in view of applicants' amendment to the claim filed 07/30/2008.

4. The rejection of Claims 1-6 under 35 USC 101 as being directed to non-statutory subject matter has been withdrawn in view of applicants' amendments to the claims filed 07/30/2008.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein comprising the amino acid sequence of SEQ ID NO: 3 and having endoglucanase activity; does not reasonably provide enablement for any homologous protein having endoglucanase activity and comprising an amino acid sequence having at least 85% homology to SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

commensurate in scope with these claims. The arguments filed 07/30/2008 have been considered but are not persuasive for reasons of record as supplemented below.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

MPEP§ 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the claims encompass any homologous protein having endoglucanase activity and comprising an amino acid sequence having at least 85% homology to SEQ ID NO: 3.

The reference of Chica et al. (Curr Opin Biotechnol. 2005 Aug;16(4):378-84; reference of record) teaches that the complexity of the structure/function relationship in enzymes has proven to be the factor limiting the general application of rational enzyme modification and design, where rational enzyme modification and design requires in-depth understanding of structure/function relationships. The reference of Sen et al. (Appl Biochem Biotechnol. 2007 Dec;143(3):212-23; PTO 892) teaches *in vitro* recombination techniques such as DNA shuffling, staggered extension process (StEP), random chimeragenesis on transient templates (RACHITT), iterative truncation for the creation of hybrid enzymes (ITCHY), recombined extension on truncated templates (RETT), and so on have been developed to mimic and accelerate nature's

recombination strategy However, such directed evolution techniques only enable methods for searching and screening for the recited homologous protein having endoglucanase activity and comprising an amino acid sequence having at least 85% homology to SEQ ID NO: 3.

The specification provides guidance, prediction, and working examples for an endoglucanase isolated from *staphylotrichum coccosporum* comprising the amino acid sequence of SEQ ID NO: 3. The specification, however, does not provide guidance, prediction, and working examples for making the recited homologous protein having endoglucanase activity and comprising an amino acid sequence having at least 85% homology to SEQ ID NO: 3.

The recitation of a homologous protein having endoglucanase activity and comprising an amino acid sequence having at least 85% homology to SEQ ID NO: 3. That is, the claimed proteins share at least 85% of the structure of SEQ ID NO: 3, while 15% of the structure can vary. There is no teaching in the specification regarding which 15% of the structure of the said protein having at least 85% homology to SEQ ID NO: 3 can be varied while retaining enzymatic activity. The specification does not provide a correlation between any structure, other than amino SEQ ID NO: 3, and endoglucanase activity, based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 3 without losing endoglucanase activity. Further, there is no art-recognized correlation between any structure, other than amino SEQ ID NO: 3, and endoglucanase activity, based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 3 without losing endoglucanase activity. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 3 and still retain the catalytic activity.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for any protein having endoglucanase activity and comprising an amino acid sequence having at least 85% homology to SEQ ID NO: 3. Alternatively, trial and error experimentation involves making amino acid substitutions, deletions, additions, and combinations thereof to SEQ ID NO: 3, and screening for proteins that still retain endoglucanase activity. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a skilled artisan to make and use the claimed invention. Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988).

7. Claims 1-5 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are directed toward the current USPTO Written Description Training Materials made available to the public on 04/11/2008 for information regarding examination of patent claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph.

The claims are genus claims encompassing a genus of proteins obtained from any microorganism belonging to the genus *Staphylotrichum* having endoglucanase activity of any amino acid sequence for which no structure is apparent obtained from any microorganism belonging to the genus *Staphylotrichum*, and a genus of proteins having endoglucanase activity and comprising an amino acid sequence having at least 85% homology to SEQ ID NO: 3. The scope of each genus includes many members with widely differing structural, chemical, and physiochemical properties such as widely differing amino acid sequences and biological functions. Furthermore, each genus is highly variable because a significant number of structural and biological differences between genus members exist.

The recitation of a homologous protein having endoglucanase activity and comprising an amino acid sequence having at least 85% homology to SEQ ID NO: 3. That is, the claimed proteins share at least 85% of the structure of SEQ ID NO: 3, while 15% of the structure can vary. However, there is no teaching in the specification regarding which 15% of the structure of

the said protein having at least 85% homology to SEQ ID NO: 3 can be varied while retaining enzymatic activity.

While the specification discloses an endoglucanase isolated from *staphylotrichum coccosporum* comprising the amino acid sequence of SEQ ID NO: 3, the specification, however, does not describe and define any structural features, amino acid sequences, and/or biological functions that are commonly possessed by members of each genus. The specification does not provide a correlation between any structure, other than amino SEQ ID NO: 3, and endoglucanase activity, based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 3 without losing endoglucanase activity. Further, there is no art-recognized correlation between any structure, other than amino SEQ ID NO: 3, and endoglucanase activity, based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 3 without losing endoglucanase activity. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 3 and still retain the catalytic activity. Although the claims recite that the protein is obtained from a microorganism belonging to the genus *Staphylotrichum* and comprises partial amino acid sequence of SEQ ID NO: 1 , fully distinguishing amino acid sequences and structures responsible for endoglucanase activity have not been adequately disclosed.

MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification fails to disclose additional endoglucanases encompassed by the claims. As such the disclosure of the above mentioned endoglucanase isolated from *staphylotrichum coccosporum* comprising the amino acid sequence of SEQ ID NO: 3 is insufficient to be representative of the attributes and features common to all the members of each claimed genus.

Vas-Cath, Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at

page 1116). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class, where the specification provided only the bovine sequence.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of each claimed genus.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 5, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasmussen et al. (WO 91/17243, published 11/14/1991; PTO 1449 from IDS filed 06/05/2006).

Rasmussen et al. teach a protein having endoglucanase activity which is produced by a recombinant process in host cells, a cellulase preparation comprising said endoglucanase, and detergent composition comprising said endoglucanase (see entire publication, especially pages 4-12, pages 14-46, and claims 1-9 and 16-26). Regarding claim 16 no patentable weight is given to the process for making the endoglucanase since there are no structural difference between the produced protein of claim 16 and the reference protein taught by Rasmussen et al. Thus, the reference teachings anticipate the claimed invention.

The arguments filed 07/30/2008 have been fully considered but are not persuasive. Although the claims recite "obtained from" and "derived from" without any specific recitation of the amino acid sequences and structures of the claimed protein having endoglucanase activity, the claims are deemed to encompass any endoglucanase irrespective of its amino acid sequence and structure. The claims as amended do not recite any distinguishing amino acid sequences and structures responsible for endoglucanase activity, and thus, are anticipated by the teachings Rasmussen et al.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Primary Examiner
Art Unit 1652